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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,767	05/14/2001	Isao Horiuchi	HORIUCHI-6	9992

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,767

Applicant(s)

HORIUCHI, ISAO

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment filed on November 18, 2004. Claims 9-12 are pending. Claim rejection made under 35 U.S.C. § 103(a) is withdrawn and modified to address the newly added limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al. (JP408198724A) ("Yokoi") in view of Ogawa (JP411228439A).

Yokoi teaches skin cosmetic composition 0.001-20 % of supernatant liquid of culture of lactic acid bacteria. See Constitution. The reference teaches that the composition, which also contains hyaluronic acid or its salt, has "excellent massaging effect" and "high moisture retention" properties, among others. The reference further teaches that the composition "is usable with ease without damaging skin by action of hyaluronic acid".

While the reference does not mention "a agent for stabilizing living cells with adjustment of cytolysis action of the cells by said protease", it is well settled in patent law that a compound and its properties are inseparable. See In re Papesch, 315 F.2d, 381, 137 U.S.P.Q. 43 (C.C.P.A., 1963). Thus, the recited "agent" must be also present in the Yokio culture supernatant.

The Yokoi reference does not teach a protease.

Ogawa teaches a topical composition comprising an extract from the mycelia of *Agaricus blazei* Murill in combination with other skin care actives. See Abstract. The reference teaches that the mycelia extract is used in the amount of 0.0001-5 wt %. See Solution. See instant claim 12. The reference teaches that the composition is effective for prevention/improvement of skin aging symptoms. The composition also contains hyaluronic acid. While the reference does not explicitly teach that the protease has cell-decomposing activities, this limitation is directed to the properties of the prior art compound. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, applicants use the same extract of mycelium culture filtrate of *Agaricus blazei* Murill used in Ogawa. It cannot be said that the Ogawa protease somehow does not have the decomposing-cell activity which applicants' protease has because both the prior art and applicants' inventions employ the same compounds.

Claim 9 recites a process limitation which describes how the claimed cell culture is prepared. Examiner respectfully points out that the court in In re Thorpe held, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the production in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777

F.2d 695, 698, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). In this case, the claims are directed to a composition. The proposed limitation of the process of which how the culture supernatant is obtained is not given patentable weight because the composition itself is viewed an obvious variation of the prior arts, and the patentability of the composition does not depend on the process of making the product. How the culture supernatant is prepared does not change the fact that the culture supernatant is well known in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Yokoi and Ogawa because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. See In re Kerkhoven, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). Both the Yokio bacteria cell supernatant and the Ogawa protease are used for skin care purposes, and thus it is prima facie obvious to combine these ingredients to make a third skin care cosmetic composition.

Alternatively, the skilled artisan would have been motivated to modify the Yokio composition by adding the extract of mycelia of *Agaricus blazei* Murill as motivated by Ogawa because 1) both references are directed to skin care compositions utilizing hyaluronic acid, 2) Ogawa specifically teaches that the protease improves skin aging symptoms. The skilled artisan thus would have had a reasonable expectation of successfully producing a skin care composition which is has good massaging effect, high moisture retention effects, and anti-aging effects.

Response to Arguments

Applicant's arguments filed November 18, 2004 have been fully considered but they are moot in view of new grounds of rejections in part and unpersuasive in part.

Applicants assert that in order to make a prima facie case of obviousness, the Office must show "a reasonable expectation of obtaining applicant's results". Examiner respectfully points out that the legal standard only requires a reasonable expectation of success of combining the references. The law does not call for the Office to show that the combined references explicitly indicate all the properties of the prior art inventions which would be otherwise be obvious. In this case, there is a reasonable expectation of successfully combining the Yokoi and Ogawa composition because both references teach topical compositions comprising hyaluronic acid.

Applicants assert that "when an enzyme is extracted, it is necessary to carry out the extraction under conditions" such as adjusted pH, selection of an extraction solvent, setting of the extraction temperature or the likes. However it is noted that the pH range, extraction solvent and extraction temperature are not even recited in the claims.

In response to applicants' argument that that the language in claim 9 characterize the product. As stated in the rejection, "being obtained after removing bacterial cells from a culture filtrate of lactic acid bacteria obtained by culturing the lactic acid bacteria" is strictly directed to the process of how the culture supernatant is obtained. The recited language here does not define what the lactic acid bacteria culture supernatant is, nor how the applicants' culture supernatant is structurally different from the Yokoi supernatant liquid of culture of lactic acid bacteria. Examiner

recognizes that the terms such as "interbonded to one another", "intermixed", "ground in place", etc, indicates physical and structural properties of a product. How the supernatant of the bacterial cell is obtained does not render such limitation which distinguishes the claimed component from the prior art.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

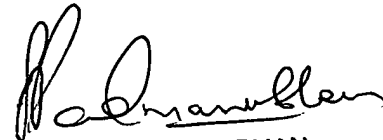
Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER